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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,043	04/05/2002	Vincent L Chiang	066040-9675	9579

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/980,043

Applicant(s)

CHIANG ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 167-169, 171-183, 187, 188, 191-200 and 202-214 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 173-175, 179, 180, 183, 187, 188, 191, 193-198, 204-206 and 211 is/are allowed.
- 6) ☒ Claim(s) 167-169, 171-172, 176-178, 181-182, 200, 202-203, 207-210, 212-214 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's response of 04/25/05 and the supplemental response of 06/07/05 in reply to the final Office action mailed 02/23/05 have entered. However, upon further search and consideration, it has been determined that the finality of the rejection of the last Office action be withdrawn. The indicated allowability of claims 167-169 has been withdrawn. The Office action contains NEW GROUNDS OF REJECTIONS and is made non-final. Any inconvenience the delay may have caused Applicant is deeply regretted.

Claims 167-169, 171-183, 187-188, 191-200, 202-214 are pending and are examined.

### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 167-169 and 212-214 are rejected under 35 U.S.C. 102(a) as being anticipated by Wu et al (Accession No. AF072131 deposited 23 June 1998).

The claims are drawn to an isolated polynucleotide encoding a polypeptide comprising amino acid residues from position 220 to position 749 of SEQ ID NO: 2, wherein the polypeptide has cellulose synthase activity, a polynucleotide comprising nucleotides from position 660 to position 2250 of SEQ ID NO: 1, or the nucleotides from position 69 to position 3005 of SEQ ID NO: 1, and the polynucleotide of SEQ ID NO: 1 encoding SEQ ID NO: 2.

Wu et al teaches an isolated polynucleotide from developing secondary xylem (wood) stem of Aspen (*Populus tremuloides*) which is identical to Applicant's SEQ ID

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NO: 1 encoding SEQ ID NO: 2. Therefore, the claimed invention is taught in the prior art.

MPEP 2132 states (T) he term "others" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be "by others." This holds true for all types of references eligible as prior art under 35 U.S.C. 102(a) including publications as well as public knowledge and use. In the instant application, the Applicant Daniel T. Carraway is not listed as one authors of the cited reference.

A 37 CFR 1.131 affidavit can be used to overcome the above rejection. See, In re Foster, 343 F.2d 980, 145 USPQ 166 (CCPA 1965). In re Facius, 408 F.2d 1396, 161 USPQ 294 (CCPA 1969). See also MPEP § 715 for information on when an affidavit under 37 CFR 1.131 can be used to overcome a reference and what evidence is required.

### ***Written Description***

Claims 171-172, 176 -178, 181-182, 200, 202-203 and 207-210 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 02/23/05. Applicant's arguments filed 04/25/05 have been considered but are not deemed persuasive.

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Applicant asserts that the claims as currently amended satisfy the written description requirement. This assertion is incorrect because the amendment to claims 171-172, 176-178, 181-182, to recite, "comprising" or "consisting of" does not necessarily imply that the sequence has a complete structure and hence has functional cellulose synthase activity. The specification fails to describe SEQ ID NO: 5, its UDP-binding domain, or the ability of said UDP-binding domain to function independently as cellulose synthase when expressed in a transgenic plant. SEQ ID NO: 4 is a partial DNA (it does not possess a complete open reading frame) encoding a partial protein having no known function. A polynucleotide comprising SEQ ID NO: 4 reads on fusion genes, cDNAs, and constructs having SEQ ID NO: 4 in common, which Applicant was not in possession at the time the application was filed. The instant specification describes a polynucleotide comprising the UDP-glucose binding domain of SEQ ID NO: 2 that is capable of cellulose synthase activity, transgenic plant comprising it and a method that employs said polynucleotide. SEQ ID NO: 1 is from Aspen tree while SEQ ID NO: 4 is from Arabidopsis. Because SEQ ID NO: 4 is a partial DNA and no cellulose synthase activity has been disclosed, the written description requirement of SEQ ID NO: 4 encoding SEQ ID NO: 5 has not been satisfied. Since Applicant has not described SEQ ID NO: 4 encoding SEQ ID NO: 5, vectors, plants plant cells/seed comprising SEQ ID NO: 4 and methods that employ SEQ ID NO: 4 are similarly not described as stated in previous Office actions. Therefore, contrary to Applicant's arguments, Examiner has clearly set forth sufficient reasons to support the lack of written description.

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Applicant correctly states that it is not necessary for an Applicant to actually reduce to practice the invention to satisfy the written description requirement. However, MPEP 2163 states, "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art." In this application, Applicant has provided no evidence to support the conclusion that the partial DNA of SEQ ID NO: 5 encodes a functional cellulose synthase.

Therefore, weighing all factors above and in the last Office actions, the claimed invention does not meet the current written description requirements.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 192 and 199 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a transgenic plant cell comprising the antisense of SEQ ID NO: 1, does not reasonably provide enablement for a method that employs the antisense of all nucleotide sequences encoding SEQ ID NO:

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2 or amino acid residues from position 220 to position 749 of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for producing a transgenic plant cell comprising introducing into the plant cell an exogenous polynucleotide comprising the antisense of a polynucleotide encoding SEQ ID NO: 2 or amino acid residues from position 220 to position 749 of SEQ ID NO: 2.

The specification, however, is not enabling for antisense inhibition of the nucleotide sequences as broadly claimed. The specification teaches the antisense of SEQ ID NO: 1. The state of the art teaches that a high level of sequence identity must exist between the antisense nucleic acid and the target molecule for effective inhibition of expression to occur. Given the degeneracy of the code, many of the nucleotide sequences that encode SEQ ID NO: 2 share relatively little sequence identity, and are significantly divergent from the nucleotide sequence of SEQ ID NO: 1. Applicant provides no guidance for inhibition of nucleotide sequences other than SEQ ID NO: 1 by antisense technology.

The state of the prior art teaches unpredictability in the inhibition of expression of specific coding sequence via antisense RNA in transgenic plants, due to the variation in the degree of antisense inhibition which resulted in different transgenic clones (see BIRD et al, Biology and Genetic Review, vol. 9, pages 207-227 (1991). See also, Smith et al (Nature, Vol. 334, pp. 724-726 (1988) who teach the antisense expression of

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tomato polygalacturonase gene does not produce the predicted change in fruit ripening (page 725, paragraph bridging columns 1 and 2).

Furthermore, since the working example disclosed in the specification is limited to the antisense of SEQ ID NO: 1; the antisense inhibition activity of SEQ ID NO: 1 cannot be extrapolated to all nucleotide sequences encoding SEQ ID NO: 2, given the unpredictability inherent in the inhibition by antisense mechanisms as discussed above.

Therefore, given the breadth of the claims; the lack of guidance as discussed supra; the unpredictability in antisense inhibition; and the limited working examples, the claimed invention is not enabled throughout the broad scope. *In re Wands* (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988))

#### **Remarks**

The polynucleotide sequence of SEQ ID NO: 4 encoding SEQ ID NO: 5 is deemed free of the prior art.

Claims 173-175, 179-180, 183, 187-188, 191, 193-198, 204-206, and 211 are allowed.

#### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

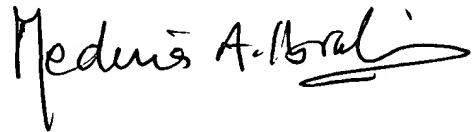


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/5/05

Mai

A handwritten signature in black ink, appearing to read "Medina A. Ibrahim", with a stylized flourish at the end.

**MEDINA A. IBRAHIM  
PATENT EXAMINER**